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In re Application of: John W. Evans, et al

Docket No.: 97541.00011

Serial No.: 09/935,982

Confirmation No.: 2288

Filing Date: August 23, 2001

Art Unit: 1751

Title: Non-Aqueous Heat Transfer Fluid and Use Thereof

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**ATTACHED HERETO:**

1. Revised Section of Appellant's Appeal Brief (24 pages)

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**  
**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of: John W. Evans	)	Examiner:	G. Del Cotto
	)		
Serial No.: 09/935,982	)	Confirmation No.:	2268
	)		
Filing Date: 8/23/2001	)	Group Art Unit:	1751
	)		
For: Non-Aqueous Heat Transfer Fluid and Use Thereof	)	Docket No.:	97541.00011

Dated at Hartford, Connecticut, this 18th day of March, 2008

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Commissioner for Patents  
P.O. Box 1450  
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**REVISED SECTION OF APPELLANT'S APPEAL BRIEF**

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ME1 722112v.1

Appellant submits these revised section VII of its appeal brief in response to the Office Communication dated March 5, 2008. Appellant has revised this section to provide a heading in the Argument section corresponding to each grounds to be reviewed on appeal. As instructed in the Office Communication, only the section found defective is being provided in this paper.

## **VII. ARGUMENT**

### **Introduction**

The claimed invention is directed to a method for reducing the oral toxicity of an ethylene glycol based, non-aqueous heat transfer fluid. As discussed in the specification at, for example, paragraphs 0003 and 0011-0014, ethylene glycol is commonly used in heat transfer fluids in internal combustion engines. Ethylene glycol is typically mixed with water in these applications, and corrosion inhibitors and other additives are added to the heat transfer fluid.

One drawback of ethylene glycol based heat transfer fluids is that ethylene glycol is considered a dangerous material due to its toxicity. Paragraphs 0011-0014. The lethal dose of ethylene glycol in humans is approximately 1,570 mg/kg body weight. While replacements for ethylene glycol, such as for example propylene glycol, have been explored, the cost of the alternatives has prevented widespread usage.

The present invention is a method for producing a non-aqueous, ethylene glycol based heat transfer fluid having reduced toxicity. The present inventors found that adding relatively small amounts of propylene glycol to an ethylene glycol based heat transfer fluid unexpectedly reduced the oral toxicity of the resulting fluid to levels far lower than the toxicity predicted by the standard formula used by the art based upon the toxicities of the individual components. Paragraphs 0066-0080.

As recited in claim 30 as amended, the method comprises mixing a non-aqueous, ethylene glycol based heat transfer fluid with propylene glycol to achieve a propylene glycol concentration of between about 5 percent by weight and 30 percent by weight of the total weight of the ethylene glycol and propylene glycol in the resulting non-aqueous heat transfer fluid. Claim 30 further recites that the non-aqueous heat transfer fluid resulting from combining the ethylene glycol based fluid and the propylene glycol is less toxic than 10,000 mg/kg on the basis of an acute LD<sub>50</sub> oral toxicity in rats. Claim 30 further recites that the resulting non-aqueous fluid contains at least one corrosion inhibiting additive that is soluble in both ethylene glycol and propylene glycol, and that the resulting heat transfer fluid contains no additive that requires water to dissolve the additive or to enable the additive to function.

Claims 40-45 all depend from claim 30 and recite further embodiments of the invention containing specific corrosion inhibiting additives.

**Rejection of Claims 30 and 40-45 Under 35 U.S.C. § 112**

Claims 30 and 40-45 stand rejected under 35 U.S.C. § 112 first paragraph on the grounds that the specification does not provide a basis for the limitation "less toxic than 10,000 mg/kg on the basis of an acute LD<sub>50</sub> oral toxicity". The Examiner agrees that the specification provides basis for the 10,000 mg/kg limitation, but states that "it does not provide basis for less toxic than 10,000 mg/kg" because it would "encompass amounts such as 20,000 mg/kg, 50,000 mg/kg, 100,000 mg/kg, etc. and has no [upper] limit." As discussed below, when this limitation is considered in the context of the invention and the specification it is clear that there is support for this limitation in the specification. The phrase cited by the Examiner appears in a limitation that recites "wherein the resulting fluid is less toxic than 10,000 mg/kg on the basis of an acute LD<sub>50</sub>

oral toxicity in rats." Thus, the recited limit must be read as it applies to the LD<sub>50</sub> value in rats, not simply standing alone.

Under the written description requirement of §112, the applicant must provide a sufficient description to allow one skilled in the art to recognize that the applicant possessed the claimed invention at the time of filing. Union Oil Co. of California v. Atlantic Richfield Co., 208 F.3d 989, 997 (Fed. Cir. 2000). "The possession test requires assessment from the viewpoint of one of skill in the art." Pandrol USA, LP v. Airboss Railway Products, Inc., 424 F.3d 1161, 1165 Fed. Cir. 2005). It is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention at the time of filing. Lizardtech, Inc. v. Earth Resource Mapping, Inc., 424 F.3d 1336, 1345 (Fed. Cir. 2005). "The law is clear that patent documents need not include subject matter that is known in the field of the invention and is in the prior art, for patent are written for persons experienced in the field of the invention." S3 Inc. v. Nvidia Corp., 259 F.3d 1364, 1371 (Fed. Cir. 2001). "The specification would be of enormous and unnecessary length if one had to literally reinvent and describe the wheel." Atmel Corp. v. Information Storage Devices, Inc., 198 F.3d 1374, 1382 (Fed. Cir. 2001).

As described in the specification at paragraph 0011, and as understood by those skilled in the art, the LD<sub>50</sub> value for oral toxicity is the dosage at which 50 percent of the rats fed a particular substance die. The quantity fed to each rat is measured as a dosage in mg (composition)/kg (rat weight). If the dosage is greater than the LD<sub>50</sub> value, then 50 percent or more of the dosed rats would be expected to die. On the other hand, if the dosage is less than the LD<sub>50</sub> value, fewer than 50 percent of the dosed rats would be expected to die. A lower LD<sub>50</sub> value indicates higher toxicity (i.e. smaller amounts of the substance can be lethal). Therefore,

the limitation in claim 30 means that the fluid produced by the claimed methods must have a toxicity rating of at least 10,000 mg/kg based upon the LD<sub>50</sub> value for oral toxicity in rats.

In the context of an LD<sub>50</sub> value limiting oral toxicity as in this case, the limitation defines the amount of the heat transfer fluid which can be fed to a rat and result in the death of half of the rats or less. If an ethylene glycol based heat transfer fluid has an LD<sub>50</sub> value higher than the recited limit of claim 30, the material meets the limitation regardless of the actual value.

The high oral toxicity of ethylene glycol is discussed in paragraphs [0011-0015] of the specification. Paragraph [0015] explains that propylene glycol is "considered essentially non-toxic". Mixtures of ethylene glycol and propylene glycol would be expected to be lower in toxicity than ethylene glycol alone due to dilution. The LD<sub>50</sub> values predicted by the art for mixtures of ethylene glycol and propylene glycol, shown graphically in Figures 2 and 3, use the formula described in paragraphs [0068-0073]. The higher the LD<sub>50</sub> value, the lower the toxicity. From Figures 2 and 3 it is clear that the predicted LD<sub>50</sub> values for ethylene glycol concentrations between 95 percent and 70 percent (i.e. propylene glycol concentrations from 5 percent to 30 percent) vary from about 6,000 mg/kg (30% propylene glycol) to slightly above 4,700 mg/kg (5% propylene glycol).

As described in the specification, the inventors discovered that this value was unexpectedly *increased* as compared to the predicted values (i.e. more of the fluid could be fed to rats without harm) by adding relatively small amounts of propylene glycol to the ethylene glycol based fluid. In this context, the limitation requiring that the fluid be less toxic than 10,000 mg/kg is fully supported, as the tests described in the specification demonstrated that the fluid had an LD<sub>50</sub> value for oral toxicity in rats of at least this amount. As pointed out in the specification at paragraph 0075, in tests using 70% by weight ethylene glycol and 30% by weight

propylene glycol (based upon the total weight of the two glycols), it was not possible to determine the LD<sub>50</sub> value of the fluid because no rat deaths occurred at doses of 21,000 mg/kg, the maximum amount that could be fed to the rats, while fluids containing 95% by weight ethylene glycol and 5% by weight propylene glycol had an LD<sub>50</sub> value "somewhere near" 15,000 mg/kg. There were no rat mortalities at the 10,000 mg/kg dosage level, absolutely establishing that the LD<sub>50</sub> value was greater than 10,000 mg/kg.

The Examiner is concerned that claim 30 encompasses toxicities that are less than an LD<sub>50</sub> value of 10,000 mg/kg. It is proper that the claim does so. Indeed, the specification explains that the toxicity of a mixture of 70% by weight ethylene glycol and 30% by weight propylene glycol cannot be calculated because no rat deaths occurred at a dosage of 21,000 mg/kg, the maximum that could be fed to the rats. This fluid is less toxic than an LD<sub>50</sub> value of 21,000 mg/kg, and of course also less toxic than 10,000 mg/kg.

The limitation of claim 30 requires that at least 10,000 mg/kg of the composition can be fed to a population of rats, and that such a dosage will cause no more than 50 percent of the rats to die. One skilled in the art would understand that this is the meaning of the limitation in view of the description in the specification, and the test results described in the specification at paragraphs 0075-0080 clearly demonstrate that the inventors were in possession of the invention at the time of filing the application. This is all that is required under the written description requirement of 35 U.S.C. § 112, first paragraph.

Accordingly, for at least the reasons stated above, claims 30 and 40-45 as currently presented are fully supported in the specification, and the rejection under 35 U.S.C. § 112 should be withdrawn.

**Rejection of Claims 30 and 40-45 Under 35 U.S.C. §§ 102(b) Based Upon Reny**

Claims 30 and 41-45 stand rejected under 35 U.S.C. § 102(b) as anticipated by Reny, WO89/09806. To anticipate a claim under Section 102(b), a single prior art reference must disclose each and every element set forth in the claim. Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987); MPEP § 2131. Reny does not recognize the problem of the oral toxicity of ethylene glycol at all, much less describe a method for reducing the toxicity of ethylene glycol. Moreover, Reny does not disclose any composition that meets all of the limitations of claim 30 as amended. Specifically, Reny does not disclose a non-aqueous heat transfer fluid comprising ethylene glycol and propylene glycol that contains no additives requiring the presence of water to dissolve the additive or to enable the additive to perform its intended function.

When Reny is read in full in view of what was known to those skilled in the art at the time that the present application was filed, it is plain that Reny does not anticipate the present claims. At page 6 of the Office Action, the examiner states that Reny at p. 3 lines 1-15 describes an embodiment that "contains no water." In fact, Reny does not describe any specific embodiment that contains no water. Moreover, all of the embodiments described by Reny for a heat transfer fluid containing ethylene glycol and propylene glycol also contain added water.

The composition described at page 3 of Reny comprises "at least 90 weight percent of an alkylene glycol or a mixture of two or more alkylene glycols" and "from 0 to 3 weight parts of phosphoric acid." Reny does not describe on page 3 which embodiments of the invention may contain no added phosphoric acid. However, Reny later explains that phosphoric acid is added "to maintain the pH of the coolant composition in the range of from 7 to 9, preferably from 7 to 8, and *only if necessary*." Reny, p. 5, lines 22-24 (emphasis added). For phosphoric acid to



function in a manner as to affect pH, water must be included in order for the phosphoric acid to ionize. See Declaration of John Evans dated January 23, 2007 at ¶ 3 (Evidence Appendix at Exhibit 1). Therefore, *the fluid described in Reny contains no water only when phosphoric acid is not necessary for the control of pH.*

The composition described in lines 1-15 on page 3 of Reny and cited by the Examiner does not mention alkaline buffers. However, later in the specification, Reny states that if the composition is too acidic, "sodium or potassium hydroxide [should be added] until a pH of from 7 to 9 is reached." Reny, p. 6, lines 3-5. Sodium hydroxide and potassium hydroxide are alkaline buffers that also require water in order for them to function.

The set of alkylene glycols is very large and is comprised of ethylene glycol, diethylene glycol, triethylene glycol, tetraethylene glycol, propylene glycol, dipropylene glycol, hexylene glycol, 2 ethyl-1,3-hexanediol, 1,5-pentanediol, *and many others*. Reny also adds glycerol (which has three hydroxyl groups) to the list by referring to it as an alkylene glycol. Reny, page 4, lines 3-4. There may be alkylene glycols or mixtures of them for which buffering would not be necessary. Indeed, on p. 5 lines 24-26, Reny says that "Some alkylene glycol mixtures are within the pH limits, and in such cases no pH adjustment is required." Reny, however, does not specify or identify any glycols or mixtures that do not require pH adjustment. Rather, Reny, by his examples in the specification, teaches that for mixtures containing propylene glycol and ethylene glycol, the addition of phosphoric acid is necessary for pH control. Reny, pages 7-9.

Phosphoric acid, the use of which is taught by Reny in heat transfer fluids comprising ethylene glycol and propylene glycol, is an undesirable ingredient in the claimed non-aqueous heat transfer fluid for a number of reasons. In order for the phosphoric acid to perform its function as an acid, there must be sufficient water added for the phosphoric acid to ionize.

Ionized phosphoric acid forms phosphate compounds with engine metals such as iron. The resulting phosphate compounds have limited solubility and will precipitate in a low water environment, such as in a non-aqueous heat transfer fluid. For example, a manufacturer of heat transfer fluid additives, Penray Companies, Inc., states that "Silicate and phosphate, while valuable as corrosion inhibitors in engine coolant, have limited solubility. That meant that if the antifreeze . . . got too concentrated in the coolant [i.e. there is not sufficient water, as in a non-aqueous heat transfer fluid], then the excess phosphate and/or silicate would drop out of the coolant." See <http://www.penray.com/managex/index.asp?x=322&y=323&articlesource=323>. (Evidence Appendix Exhibit 2).

Although Reny states that some undefined compositions might not require added water, the more important teaching of Reny, which is directly relevant in this case, is that *the compositions should not be too alkaline or too acidic*. Reny states that if the compositions are too acidic or too alkaline, they should be buffered to give them a pH in the range of 7 to 9. Whether buffered by phosphoric acid (to make the composition less alkaline) or by sodium or potassium hydroxide (to make the compositions more alkaline), water is required in the composition in order for the buffer to function. Specifically, Reny teaches that compositions of propylene glycol and mixtures of propylene glycol and ethylene glycol must contain phosphoric acid and, of course, water. In contrast, the Applicant teaches that for the claimed non-aqueous heat transfer fluid, buffering is unnecessary and water should never be added for any reason at all.

To anticipate a claim under Section 102(b), a single prior art reference must disclose each and every element set forth in the claim. Apple Computer, Inc. v. Articulate Systems, Inc., 234 F.3d 14 (Fed. Cir. 2000); Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631

(Fed. Cir. 1987); MPEP § 2131. Reny's general statement that some undisclosed combinations of alkylene glycols might not require buffering, or that some undisclosed combinations of alkylene glycols might not require added water, is insufficient to anticipate the claims on appeal. As discussed above, all of the heat transfer fluids described by Reny that contain propylene glycol contain a phosphoric acid buffer and added water. Because Reny does not describe a heat transfer fluid comprising propylene glycol, or propylene glycol and ethylene glycol, that contains less than 0.5% by weight water and no additives requiring added water to dissolve or function, Reny does not anticipate claims 30 and 41-45.

The examiner's conclusion on pages 5-6 of the Office Action that the coolant composition described on page 9 of Reny, which describes a coolant that contains 1 part water, anticipates the claimed invention is incorrect for at least two reasons. First, the statement at Paragraph 0093 of the present application regarding the presence of up to 0.5% water in the heat transfer fluid of the present invention refers to water present *as an impurity*. No water is added to the composition, and indeed no added water is required because the heat transfer fluid does not contain any additives requiring water to be present in the fluid. The fluid described at page 9 of Reny comprising ethylene glycol, propylene glycol and corrosion inhibitors includes added water to hydrolyze the phosphoric acid present in the composition.

The Examiner's assertion on page 6 of the Office Action that Reny's page 9 teaches propylene glycol and propylene glycol/ethylene glycol compositions that contain little or no water is wrong because the only compositions shown with less than 1% water are pure propylene glycol without additives (designated as C<sub>1</sub>) and a mixture of propylene glycol and ethylene glycol without additives (designated as C<sub>2</sub>). Both C<sub>1</sub> and C<sub>2</sub> have asterisks that indicate that neither is "an example of the invention" described by Reny. These compositions were provided

for comparison only, and the results show that they are not practical as heat transfer fluids because they are highly corrosive.

The only fluids described by Reny which could be used as heat transfer fluids are designated Example 1 and Example 2. Example 1 is a fluid containing only propylene glycol as a heat transfer medium and example 2 is a fluid containing both propylene glycol and ethylene glycol as a heat transfer medium. The fluids of examples 1 and 2 of Reny each contain 1 percent by weight water and phosphoric acid. As described by Reny, each of these fluids contains phosphoric acid and at least 0.985% water (1 part water/101.475 parts total ingredients). Thus, Reny *adds* twice the quantity of water that the present application states can be present *as an impurity*. When Reny is read as a whole, therefore, he plainly teaches that heat transfer fluids comprising ethylene glycol and propylene glycol require phosphoric acid buffers and added water. The addition of water and buffers to such fluids was consistent with the understanding of those skilled in the art at the time. See Declaration of John Evans dated January 23, 2007 at ¶ 4 (Evidence Appendix at Exhibit 1).

**Rejection of Claim 40 Under 35 U.S.C. § 103(a) Based Upon Reny**

The Examiner states at pages 6-7 of the Office Action that claim 40 is rejected under 35 U.S.C. § 103(a) based upon Reny because it would have been obvious to one skilled in the art to reduce the toxicity of ethylene glycol by mixing ethylene glycol with a polyhydric alcohol such as glycerol. Applicants note that claim 40 was previously amended and no longer recites the combination of ethylene glycol with a polyhydric alcohol such as glycerol. Rather, claim 40 as currently presented recites a composition comprising ethylene glycol and between 5 percent and 10 percent by weight propylene glycol.

A prior art reference must be considered in its entirety, including portions that lead away from the claimed invention. MPEP § 2141.03; W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art.

In re Wesslau, 353 F.2d 238, 241 (CCPA 1965). The Federal Circuit has held that it is improper to consider a single line taken out of context from a reference without considering other statements in the reference that argue against obviousness. Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 448 (Fed. Cir. 1986).

Reny does not teach or suggest the combination of ethylene glycol and propylene glycol in the amounts recited in claim 40. Moreover, as described above, Reny does not teach any combination of ethylene glycol and propylene glycol without the addition of phosphoric acid and water for any purpose, much less to reduce the oral toxicity of the resulting fluid. Reny does not even mention oral toxicity, much less teach or suggest a solution to that problem. Moreover, for at least the reasons presented in the specification at paragraphs 66-80, the reduction in oral toxicity achieved with fluid of the present was unexpected. There is nothing in Reny that would lead one skilled in the art to even attempt reduce the oral toxicity of ethylene glycol by adding the proportions of propylene glycol recited in claim 40, which unexpectedly led to a reduction in the toxicity of the fluid. See KSR International Co. v. Teleflex Inc., 127 S. Ct. 1727, 1739-40 (2007) (combination that works in an unexpected and fruitful manner is not obvious under 35 U.S.C. § 103(a)). Accordingly, claim 40 is patentable over Reny under 35 U.S.C. § 103(a).

For at least the reasons set forth above, Reny does not describe, or otherwise teach or suggest, a heat transfer fluid as defined in the specification and recited in claims 30 and 40-45

comprising ethylene glycol and propylene glycol and that does not contain any additives that require water to dissolve the additives in the fluid or to enable the additives to function in the fluid.

**Rejection of Claims 30 and 40-45 Under 35 U.S.C. § 103(a) Based Upon Meyer or Maes**

Claims 30 and 40-45 stand rejected under 35 U.S.C. § 103(a) in view of Meyer, U.S. Patent No. 5,118,434 or Maes, U.S. Patent No. 5,366,651. The three essential criteria that must each be established to substantiate a *prima facie* obviousness rejection under 35 U.S.C. § 103 are: (1) the reference must teach or suggest all the claim limitations; In re Royka, 490 F.2d 981 (CCPA 1974); (2) there must be a reasonable expectation of success; and (3) there must be some suggestion or motivation in the reference themselves or in the knowledge generally available to one of ordinary skill in the art to modify or combine reference teachings. Obviousness and expectation of success are evaluated from the perspective of a person having ordinary skill in the art at the time of the invention. Life Techs., Inc. v. Clontech Labs., Inc., 224 F.3d 1320, 1326 (Fed. Cir. 2000). There must be some suggested or reason to modify the prior art composition other than the hindsight gained from the inventor's disclosure. Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1051 (Fed. Cir. 1988). See also KSR International Co. v. Teleflex Inc., 127 S. Ct. 1727, 1739-40 (2007) (combination that works in an unexpected and fruitful manner is not obvious under 35 U.S.C. § 103(a)).

At pages 7-8 of the Office Action, the examiner states that Meyer and Maes "suggest reducing the oral toxicity of nonaqueous fluids containing ethylene glycol by mixing with ethylene glycol a specific diol such as propylene glycol in the specific proportions recited by the instant claims." This statement by the Examiner is incorrect. Neither Meyer nor Maes recognize or discuss the problem of reducing the oral toxicity of ethylene glycol based fluids, much less

describe, teach or suggest a method to reduce the toxicity of a non-aqueous ethylene glycol based fluid as recited in claim 30 as amended. Moreover, neither Meyer nor Maes describe, teach or suggest combining ethylene glycol containing fluids with propylene glycol in any specific proportions, much less the specific proportions recited in claim 30 as amended, which results in a fluid having an unexpectedly large decrease in oral toxicity. At most, Meyer and Maes describe broad generic formulations that may, in some instances which are not specifically taught or described in either reference, encompass some of the fluids produced by the claimed methods. This is insufficient to support the rejection of the claims based upon either Meyer or Maes. See In re Baird, 16 F.3d 380, 382 ("The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious."); MPEP § 2144.08..

At page 13 of the Office Action, the Examiner states that it would have been obvious to combine ethylene glycol and propylene glycol because each had previously been used in anti-freeze compositions. Where, as here, the prior art does not identify specific compositions that achieve an unexpected and desirable result, the claimed composition is patentable. The Examiner goes on to state that it is unclear what unexpected results are shown. In the specification of the present application at paragraphs 0066-0080, the applicants describe in detail that the compositions unexpectedly exhibited oral toxicity that is much lower than would have been expected.

As discussed in the specification, it had been known to those skilled in the art that the addition of a less toxic substance to a more toxic substance will result in a mixture that is reduced in toxicity compared to the toxicity of the more toxic substance as a result of dilution of the more toxic substance. The formula generally used to predict the LD<sub>50</sub> values for mixtures of substances, as published by the World Health Organization, is described in the specification at

paragraph 0068. In the case of ethylene glycol, a reduction in toxicity based only upon dilution does not result in a non-toxic or safe mixture except when the percentage of dilution is very substantial. The curve shown in Fig. 3 of the specification is generated using the formula described in the specification. In Fig. 3, the predicted LD<sub>50</sub> in rats for the claimed range of combinations of ethylene glycol and propylene glycol was about 6,000 mg/kg or less. As described in the application, laboratory testing sponsored by the applicant surprisingly revealed that fluids containing substantial percentages of ethylene glycol when mixed with propylene glycol resulted in fluids that were far less toxic than predicted due to dilution. As set forth in the specification at paragraphs 0066-0080, the inventors discovered that the claimed compositions were less toxic on the basis of an acute oral rat LD<sub>50</sub> of "somewhere near" 15,000 mg/kg or greater and absolutely less toxic on the basis of an acute oral rat LD<sub>50</sub> of greater than 10,000 mg/kg. Although the invention is not limited by any particular mechanism of action, the applicant believes that propylene glycol may act as an ADH enzyme inhibitor when it is mixed with ethylene glycol. The inhibiting action is believed to reduce or prevent the conversion of ethylene glycol to glycoaldehyde and to thereby reduce the toxic metabolites that are the essence of ethylene glycol poisoning.

Indeed, many skilled in the art still do not understand that combining propylene glycol with ethylene glycol will reduce the toxicity of the fluid well below the predicted toxicity for a given combination. As set forth in the January 23, 2007 Declaration of John Evans in paragraphs 8 and 9 (Evidence Appendix Exhibit 1), many still believe that combining any amount of ethylene glycol with a propylene glycol based fluid will "eliminate the safety advantages" of the propylene glycol fluid. As described above, the present inventors discovered that, to the contrary, addition of relatively small amounts of propylene glycol to an ethylene glycol based



fluid unexpectedly reduced the oral toxicity of the fluid to a level that was not predicted, and that, in some cases, was actually less than the toxicity of the pure propylene glycol.

Regardless of the mechanism of action, where, as here, a claimed range achieves unexpected results, the claimed range is patentable over a prior art description of generic ranges. In re Woodruff, 919 F.2d 1575 (Fed. Cir. 1990); MPEP § 2144.05. For at least these reasons, in addition to the reasons reiterated below, the claims as amended are not obvious under 35 U.S.C. § 103(a) in view of Meyer and Maes.

In addition to the reasons discussed above, Meyer does render the claims obvious because Meyer describes deicing solutions comprising alkylene glycols, water, corrosion inhibitors, and one or more polymeric additives. Meyer states at Column 2, lines 58-61 that the composition contains "up to 50 percent water" and preferably between 1 and 10 percent water by weight. Meyer does not describe a heat transfer fluid. Meyer describes a deicing fluid containing one or more polymeric additives. Meyer states at col. 1, lines 24-27 that polymeric additives are added to a deicing fluid to thicken the fluid (i.e. to increase the viscosity of the fluid). The required polymeric additives of Meyer's composition are further intended to prevent precipitation of materials contained in the composition, and precipitation of materials contained in water that may be mixed with the composition. While polymeric additives may be desirable in a deicing fluid, they are generally undesirable in a heat transfer fluid.

It is known in the art that heat transfer is improved when the viscosity of a heat transfer fluid is reduced. At paragraphs 0058-0060 of the specification, the advantages of the reduced viscosity of ethylene glycol and propylene glycol mixtures, as compared to the higher viscosity of propylene glycol alone, is discussed. In paragraph 0058, the inventors note that "viscosity at any given temperature decreased as the percentage of EG increased." Indeed, a major advantage

of combining ethylene glycol and propylene glycol in a non-aqueous heat transfer fluid is to decrease the viscosity of the propylene glycol, thereby increasing the performance of the heat transfer fluid. It would not be obvious to one skilled in the art to modify Meyer by removing the polymeric additive described for the deicing fluid in Meyer to arrive at the heat transfer fluid produced by the method of the present invention. In fact, such a modification would render Meyer unfit for use as a deicing fluid. See MPEP § 2143.01(V) and (VI) (obviousness is not established where a reference must be modified in a manner such that it will be unsatisfactory for its intended purpose or it will change the principle of operation of the reference).

Moreover, the composition described in Meyer requires the presence of added water to maintain the additives described therein in solution. Indeed, Meyer states at Col. 2, lines 59-61 that the composition preferably contains between about 1 and 10 percent by weight water. All of the fluids described in Meyer contain some added water. At col. 4, line 68 to col. 5, line 2, Meyer states: "In practice, whether used as a deicing fluid or a heat transfer fluid, the glycol-based compositions of the present invention are diluted with water." As recited in claim 30 as amended, and as described in the specification, the composition of the present invention is non-aqueous, which is defined in the specification as meaning that there is no added water, and that water is present only as an impurity. As recited in claim 30 as amended, the only additives present in the fluids formed by the method of the present invention are soluble in ethylene glycol and propylene glycol and do not require water in the heat transfer fluid to dissolve the additive or to enable the additive to function. Meyer does not teach or suggest a fluid that does not contain added water.

For at least these additional reasons, the claims as amended are not obvious under 35 U.S.C. § 103(a) in view of Meyer.

There are also additional reasons why Maes does not render the claimed methods obvious. Maes is directed to a corrosion inhibitor for use in aqueous solutions, and to antifreeze/coolant compositions containing such a corrosion inhibitor. See Maes at col. 1, line 8. Maes states that the invention described therein “is directed to a novel corrosion inhibitor composition for use in aqueous systems, an antifreeze/coolant concentrate containing the inhibitor composition and aqueous antifreeze/coolant compositions containing the inhibitor composition.” *See* Maes at col. 2, lines 54-58. Thus, Maes is directed primarily toward the corrosion inhibitor used in aqueous antifreeze/coolants.

Maes describes a fluid for use in aqueous solution comprising “a water soluble liquid alcohol freezing point depressant and a corrosion inhibitor comprising carboxylic acids or their salts and a triazole compound . . . .” Maes at col. 2, lines 62-65 (emphasis added). *See also* Maes at col. 9, lines 25-26 (claim 1 directed to a concentrate comprising “a water soluble freezing point depressant”) (emphasis added). Accordingly, Maes describes a composition having a single water soluble liquid freezing point depressant.

Maes does not teach or suggest combining ethylene glycol with propylene glycol for any purpose, much less for the purpose of forming a non-aqueous heat transfer fluid having reduced oral toxicity. At col. 3, lines 65-69, Maes states that freezing point depressants suitable for the fluid he describes are “glycol” and “glycol ethers.” These are very different chemicals.

To those skilled in the art, the term “glycol” in the singular means ethylene glycol, a polyhydric alcohol with direct bonding between the carbon atoms. For example, in the Handbook of Chemistry and Physics, 42<sup>nd</sup> ed., in the listing of Physical Constants of Organic Compounds on page 992 (Evidence Appendix Exhibit 3), the listing for “ethylene glycol” says

merely "see glycol" with no data listed. The listing for "Glycol" on page 1016 provides data only for ethylene glycol.

Glycol ethers, on the other hand, consist of hydrocarbon groups bonded through an oxygen atom. At col. 3, line 69 through col. 4, line 8, Maes states, "The glycol ethers which can be deployed as major components in the present composition include glycols such as ethylene glycol, diethylene glycol, propylene glycol, and dipropylene glycol, and glycol monoethers such as the methyl, ethyl, propyl, and butyl ethers of ethylene glycol, diethylene glycol, propylene glycol, and dipropylene glycol." The sole mention of propylene glycol by Maes appears in his listing of glycol ethers, i.e. as propylene glycol ether. Ethylene glycol, the preferred freezing point depressant in Maes, is listed at col. 3, line 67 as "glycol."

Maes nowhere describes combining ethylene glycol and propylene glycol in any proportion. At col. 3, line 67, Maes' reference to "depressants" in the plural is only in the context of introducing the listing of substances "which can be employed as major components in the present composition". Col. 3, line 68 to Col. 4, line 1. Maes does not teach or suggest using combinations or mixtures of more than one alcohol freezing point depressant. Indeed in his listing of materials that can be used as "the major component" of the fluid, Maes does not state that combinations or mixtures of the listed substances could be used in the compositions described in Maes.

Throughout the specification and claims, Maes refers solely to the use of a single water-soluble liquid alcohol freezing point depressant as the major component in the anti-freeze compositions described therein. All of the 16 examples provided by Maes contain only ethylene glycol as the alcohol freezing point depressant. See col. 5, line 3 to col. 6, line 54. In claim 1, the only independent claim in Maes, the composition is described as containing "a water soluble

alcohol freezing point depressant.” (emphasis added). Accordingly, when the specification and the claims are read as a whole, it is plain that Maes teaches only the use of a single alcohol freezing point depressant in the composition described in Maes.

At col. 3, line 65 to col. 4, line 68, Maes states “The antifreeze formulations most commonly used include water and water soluble liquid alcohol freezing point depressants such as glycol and glycol ethers.” In this sentence, Maes uses glycol, which would be understood by one skilled in the art as ethylene glycol, in the singular and glycol ethers in the plural, and throughout the specification, Maes describes antifreeze formulations containing a single glycol, indicating that only a single glycol (i.e. ethylene glycol) is used in the formulation. Thus, Maes plainly describes the use of a single glycol and Maes does not teach or suggest any combination of glycols, much less the combination and proportions recited in the claims. Indeed, as discussed above, glycol ethers are not glycols at all, and the listing of propylene glycol in Maes is within the listing of glycol ethers, i.e. propylene glycol ether. This is not propylene glycol as claimed in the claims as amended.

For at least these additional reasons, the claims as amended are not obvious under 35 U.S.C. § 103(a) in view of Maes.

**Rejection of Claims 30 and 40-45 Under 35 U.S.C. § 103(a) Based Upon Wood**

Claims 30 and 40-45 stand rejected under 35 U.S.C. § 103(a) based upon Wood, U.S. Patent No. 4,455,248. As set forth in detail below, Wood cannot be properly modified in a manner which results in the non-aqueous heat transfer fluid of the claims on appeal. The composition described by Wood “necessarily” contains sodium metasilicate. Col. 3, lines 27-55. Although Wood states that “the antifreeze may be formulated as a concentrate using little or no water”, (col. 3, lines 7-8), the requirement that the fluid described by Wood contain sodium

metasilicate necessitates the addition of sufficient water for the sodium metasilicate to dissolve and remain in solution, i.e. in order for the sodium metasilicate to function. See Declaration of John Evans dated January 23, 2007 at ¶¶ 5-7 (Evidence Appendix at Exhibit 1). As set forth in the information sheet from the Occupational Safety & Health Administration (OSHA), ([http://www.osha.gov/dts/chemicalsampling/data/CH\\_267715.html](http://www.osha.gov/dts/chemicalsampling/data/CH_267715.html)) (Evidence Appendix, Ex. 4) sodium metasilicate is not soluble in alcohols such as glycols, but is readily soluble in water. Accordingly, for at least this reason, Wood does not teach or suggest a heat transfer fluid composition as recited in the claims, which recite that the heat transfer fluids of the present invention contain no additive requiring the presence of water in the fluid to dissolve the additive or to enable the additive to function.

Despite the applicant's evidence that sodium metasilicate is insoluble in alcohols, the Examiner on page 9 states, "Note, that, while the sodium metasilicate may be soluble in alcohol, Wood clearly suggests embodiments which contain sodium metasilicate and also may contain no water." As is clear from the evidence presented by the applicant, sodium metasilicate is *not* soluble in alcohol, and the Examiner has no basis to "note" that it may be. See In re Sullivan, 498 F.3d 1345, 1351 (Fed. Cir. 2007)(evidence rebutting prima facie case of obviousness must be considered by examiner). Moreover, the "suggestion" by Wood is the statement that the concentrate "may contain little or no water." Wood does not provide any example of a heat transfer fluid containing sodium metasilicate without water, and indeed no such fluid can be formed. Wood must be read from the perspective of one skilled in the art. See Velander v. Garner, 348 F.3d 1359 (Fed. Cir. 2003)(the prior art must be viewed from the perspective of a person skilled in the art at the time of the invention). Because the undisputed evidence of record demonstrates that sodium metasilicate is not soluble in alcohol, and those skilled in the art would

immediately recognize this physical fact, Wood's statement that the concentrate *may contain no water* is untrue and cannot be relied upon to reject the claims under Section 103.

At page 6 of the Office Action, the Examiner states that Wood teaches that the compositions may contain "little or no water" in concentrates. Even in the description of the concentrates, however, Wood states that the concentrates typically contain added water. As described in the Declaration of John Evans dated January 23, 2007 at ¶ 6 (Evidence Appendix Exhibit 1), even in the concentrate form, it is necessary that the additives remain dissolved. Accordingly, to the extent that Wood suggests a concentrate having sodium metasilicate and no added water, the concentrate is not even operative for its intended purpose of awaiting the addition of water for use as a heat transfer fluid.

Moreover, Wood specifically states that in use, substantial amounts of water must be added to the fluid. This is required to ensure that water soluble additives, such as sodium metasilicate, do not precipitate out of solution in use. As described in the Declaration of John Evans dated January 23, 2007 at ¶¶ 6-7 (Evidence Appendix Exhibit 1), precipitation of water soluble additives during use is a substantial problem with heat transfer fluids which can ruin a heat transfer system. If the concentrate of Wood, which "necessarily" contains sodium metasilicate, were formulated with no water, the sodium metasilicate would not be in a dissolved form, and its direct use as a heat transfer fluid would certainly cause problems in any heat transfer system in which it was used. The sodium metasilicate would drop out and plug the flows passages of the system.

Finally, although Wood generally states that mixtures of glycols may be used in the anti-freeze compositions described therein, Wood does not teach or suggest combining ethylene glycol and propylene glycol in any specific proportions, much less in the proportions recited in

the claims on appeal. Wood is therefore insufficient to support a rejection under 35 U.S.C. § 103(a). See In re Baird, 16 F.3d 380, 382 ("The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious."); MPEP § 2144.08.

Accordingly, for at least these reasons, the rejection of claims 30 and 40-45 under 35 U.S.C. § 103(a) based upon Wood should be reversed.

#### **The Double Patenting Rejection**

The Examiner has issued a provisional double patenting rejection citing four copending patent applications. Pursuant to MPEP § 804, if this is the sole remaining rejection prior to issuance of any of the copending applications as patents, this rejection should be withdrawn in this case. While Applicants do not admit that the claims of the present invention are obvious in view of any one of those copending applications, in the event that one or more of the copending applications issues as a patent prior to this application, Applicants will file a terminal disclaimer to obviate the double patenting rejection.

No fee is believed to be required. However, if any fee is required, or otherwise if necessary to cover any deficiency in fees already paid, authorization is hereby given to charge any required fees to deposit account no. 50-3569.



Respectfully submitted,

Date: March 18, 2008

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